# NOTICES OF PROPOSED RULEMAKING

Unless exempted by A.R.S. § 41-1005, each agency shall begin the rulemaking process by first submitting to the Secretary of State's Office a Notice of Rulemaking Docket Opening followed by a Notice of Proposed Rulemaking that contains the preamble and the full text of the rules. The Secretary of State's Office publishes each Notice in the next available issue of the *Register* according to the schedule of deadlines for *Register* publication. Under the Administrative Procedure Act (A.R.S. § 41-1001 et seq.), an agency must allow at least 30 days to elapse after the publication of the Notice of Proposed Rulemaking in the *Register* before beginning any proceedings for making, amending, or repealing any rule. (A.R.S. §§ 41-1013 and 41-1022)

### NOTICE OF PROPOSED RULEMAKING

### TITLE 4. PROFESSIONS AND OCCUPATIONS

### CHAPTER 11. STATE BOARD OF DENTAL EXAMINERS

### **PREAMBLE**

<u>1.</u>	Sections Affected	Rulemaking Action
	R4-11-101	Amend
	R4-11-1301	Amend
	R4-11-1302	Amend
	R4-11-1303	Renumber
	R4-11-1303	New Section
	R4-11-1304	Renumber
	R4-11-1304	Amend
	R4-11-1305	Renumber
	R4-11-1305	Amend
	R4-11-1306	Renumber
	R4-11-1306	Amend

# 2. The specific authority for the rulemaking, including both the authorizing statute (general) and the statutes the rules are implementing (specific):

Authorizing statute: A.R.S. § 32-1207(A)(1) and (15) Implementing statute: A.R.S. § 32-1207(B)(3)(b) and (D)

# 3. A list of all previous notices appearing in the Register addressing the proposed rule:

Notice of Rulemaking Docket Opening: 8 A.A.R. 1111, March 15, 2002

# 4. The name and address of agency personnel with whom persons may communicate regarding the rule:

Name: Julie N. Chapko, Executive Director

Address: Arizona State Board of Dental Examiners

5060 N. 19th Avenue, Suite 406

Phoenix, AZ 85015

Telephone: (602) 242-1492 Fax: (602) 242-1445

E-mail: jnchapko@azbodex.com

### 5. An explanation of the rule, including the agency's reasons for initiating the rule:

The proposed rule establishes the requirements for a new oral conscious sedation permit. The Board feels that a new level of practice is necessary because of national data indicating an increase in deaths due to excessive oral sedation, including the recent deaths of six children in California. The states of Arkansas, California, North Carolina, Ohio, Oklahoma, and Oregon have made rules for oral conscious sedation. The data indicate a need for increased practitioner education and monitoring. The proposed rule amends the definition of "oral or rectal conscious sedation" and adds three new definitions to R4-11-101. Sections R4-11-1303, R4-11-1304, and R4-11-1305 are renumbered and

amended to R4-11-1304, R4-11-1305, and R4-11-1306. A new Section, Oral Conscious Sedation, is placed at R4-11-1303. The new Section establishes minimum requirements for practitioner education, training, safety, and monitoring necessary to protect the public health. Citations in Sections R4-11-1301 and R4-11-1302 are amended because of the renumbering of R4-11-1303, R4-11-1304, and R4-11-1305. Sections R4-11-1301, R4-11-1302, R4-11-1303, R4-11-1304, and R4-11-1305 are amended with changes in style, format, and grammar to comply with current requirements of the Administrative Procedure Act and the Governor's Regulatory Review Council's rules.

The Board believes that approval of these rules will benefit the public health and safety by increasing the education, training, and monitoring of dental practitioners who perform oral conscious sedation.

6. A reference to any study relevant to the rule that the agency reviewed and either proposes to rely on in its evaluation of or justification for the rule or proposes not to rely on in its evaluation of or justification for the rule, where the public may obtain or review each study, all data underlying each study, and any analysis of each study and other supporting material:

Not applicable

7. A showing of good cause why the rule is necessary to promote a statewide interest if the rule will diminish a previous grant of authority of a political subdivision of this state:

Not applicable

8. The preliminary summary of the economic, small business, and consumer impact:

The rules' impact on established Board of Dental Examiner's procedures and office-related costs is minimal. The Board's office-related costs will increase slightly to support the new permit established by the rule. The number of licensees who may apply for the new permit is estimated at 44. The estimated increase in Board revenue if all 44 dentists obtain a permit would be \$6200 per year.

The rule will only affect dentists who do not already have a 1301 permit for general anesthesia and semi-conscious sedation or a 1302 permit for conscious sedation. The initial cost of obtaining a 1303 permit for oral conscious sedation is estimated at about \$3000 with an ongoing annual cost of about \$300 to \$500.

The Board, dentists, and the public benefit from a rule that is clear, concise, understandable. The rule benefits the public health and safety by increasing the education, training, and monitoring of dental practitioners who perform oral conscious sedation.

9. The name and address of agency personnel with whom persons may communicate regarding the accuracy of the economic, small business, and consumer impact statement:

Name: Julie N. Chapko, Executive Director

Address: Arizona State Board of Dental Examiners

5060 N. 19th Avenue, Suite 406

Phoenix, AZ 85015

Telephone: (602) 242-1492 Fax: (602) 242-1445

E-mail: jnchapko@azbodex.com

10. The time, place, and nature of the proceedings for the adoption, amendment, or repeal of the rule or, if no proceeding is scheduled, where, when, and how persons may request an oral proceeding on the proposed rule:

Comments may be written or presented orally. Written comments must be received by 5:00 p.m., Monday, October 21, 2002. An oral proceeding is scheduled for:

Date: October 21, 2002

Time: 10:00 a.m.

Location: 5060 N. 19th Avenue, Suite 406

Phoenix, AZ 85015

A person may request information about the oral proceeding by contacting the person listed above.

11. Any other matters prescribed by statute that are applicable to the specific agency or to any specific rule or class of rules:

Not applicable

### 12. Incorporations by reference and their location in the rules:

None

# 13. The full text of the rules follows:

#### TITLE 4. PROFESSIONS AND OCCUPATIONS

#### CHAPTER 11. STATE BOARD OF DENTAL EXAMINERS

### **ARTICLE 1. DEFINITIONS**

Section

R4-11-101. Definitions

#### ARTICLE 13. GENERAL ANESTHESIA AND SEDATION

#### Section

R4-11-1301. General Anesthesia and Semi-conscious Sedation R4-11-1302. Conscious Sedation R4-11-1303. Oral Conscious Sedation R4-23-1303. R4-11-1304. Reports of Adverse Occurrences

<del>R4-11-1304.</del> <u>R4-11-1305.</u> Education

R4-11-1305. R4-11-1306. Renewal of Permit

### **ARTICLE 1. DEFINITIONS**

#### **R4-11-101.** Definitions

The following definitions, and definitions in A.R.S. § 32-1201, apply to this Chapter:

- + "Analgesia" means a state of decreased sensibility to pain produced by using nitrous oxide (N2O) and oxygen (O2) with or without local anesthesia.
  - "Anxiolysis" means the reduction or elimination of anxiety.
- 2. "Application" means, for purposes of Article 3 only, forms designated as applications and all documents and additional information the Board requires to be submitted with an application.
- 3. "Calculus" means a hard mineralized deposit attached to the teeth.
- 4. "Certificate holder" means a denturist who practices denture technology pursuant to A.R.S. Title 32, Chapter 11, Article 5.
- 5. "Clinical evaluation" means a dental examination of the patient named in a complaint regarding the dental condition as it exists at the time the examination is performed.
- 6. "Closed subgingival curettage" means the removal of the inner surface of the soft tissue wall of a periodontal pocket in a situation where a flap of tissue has not been intentionally or surgically opened.
  - "Combination inhalation and enteral conscious sedation" is conscious sedation induced by the administration of nitrous oxide and oxygen in combination with one or more enteral drugs or non-drug substances.
- 7. "Conscious sedation" means the use of pharmacologic or non-pharmacologic methods, or a combination of the two methods which results in minimal depression of the is a minimally depressed level of consciousness and that allows the patient to retain the ability to independently and continuously maintain an airway and respond appropriately to physical stimulation or verbal command and is induced by a drug or non-drug method or a combination of both methods.
- 8. "Controlled substance" has the meaning prescribed in A.R.S. § 36-2501(A)(3).
- 9. "Credit hour" means one clock hour of participation in a recognized continuing dental education program.
- 10. "Deep sedation" has the same meaning as "semi-conscious sedation".
- 41. "Dental laboratory technician" or "dental technician" has the meaning prescribed in A.R.S. § 32-1201(6).
- 12. "Designee" means a person to whom the Board has delegated authority to act on the Board's behalf regarding a particular task specified by this Chapter.
- 43. "Direct supervision" means, for purposes of Article 7 only, that a licensed dentist is present in the office and available to provide immediate treatment or care to a patient and observe a dental assistant's work.
- 14. "Direct supervision" means, for purposes of Article 13 only, that a licensed dentist is physically present in the operatory and actually performing dental procedures.
- 15. "Dispense for profit" means selling a drug or device for any amount above the administrative overhead costs to inventory.

### Arizona Administrative Register

# **Notices of Proposed Rulemaking**

- 16. "Documentation of attendance" means a document which that contains the following information:
  - a. Name of sponsoring entity;
  - b. Course title and synopsis;
  - e. Number of credit hours;
  - d. Name of speaker;
  - e. Date, time, and location of the course; and
  - f. Signature of person authorized to verify registration.
  - "Enteral" means an administration technique in which a drug or non-drug substance is absorbed through the oral, rectal, sublingual, or nasal mucosa.
- 17. "Epithelial attachment" means the layer of cells that extends apically from the depth of the gingival (gum) sulcus (crevice) along the tooth, forming an organic attachment.
- 18. "Ex-parte communication" means any a written or oral communication between the a decision maker, fact finder, or any Board member and one party to the proceeding, in the absence of other parties.
- 49. "Fully retired" means a dentist, dental hygienist, or denturist is at least 65 years old and has totally withdrawn from the active practice of dentistry, dental hygiene, or denturism.
- 20. "General anesthesia" means the use of any drug, element, or any other material which results in the elimination of sensations, accompanied by a state of unconsciousness is a state of unconsciousness accompanied by partial or complete loss of protective reflexes, including the inability to continually maintain an airway and to respond appropriately to physical stimulation or verbal command, that is induced by a drug or non-drug method or a combination of both methods.
- 21. "General supervision" means, for purposes of Article 7 only, the <u>a</u> licensed dentist is available for consultation, whether or not the dentist is in the office, regarding procedures or treatment which that the dentist has authorized authorizes and for which the dentist remains responsible.
- 22. "Homebound patient" means a person who is unable to receive dental care in the <u>a</u> dental office as a result of a medically diagnosed disabling physical or mental condition.
- 23. "Informal interview" means the <u>a</u> proceeding conducted under A.R.S. § 32-1263.02, during which a Board member, acting as an informal interviewing officer, and other investigators, hear testimony from the complainant, licensee, or certificate holder, and any witnesses, and receive and review evidence relating to the complaint to form findings of fact, conclusions of law, and a recommended disposition for presentation to the full Board.
- 24. "Intravenous or intramuscular sedation" means is the parenteral use of any a drug, element, or material non-drug substance to produce induce general anesthesia, semi-conscious sedation, or conscious sedation.
- 25. "Investigative interview" means a proceeding conducted under A.R.S. § 32-1263.02, during which an investigator or investigative panel hears testimony from the complainant, licensee, or certificate holder, and any witnesses, and receives and reviews evidence relating to the complaint to form findings of fact, conclusions of law, and a recommended disposition for presentation to the full Board.
- 26. "Irreversible procedure" means a single treatment, or a step in a series of treatments, which that causes change in the affected hard or soft tissues and is permanent or requires reconstructive or corrective procedures.
- 27. "Jurisdiction" means the Board's power to investigate and rule on complaints which that allege grounds for disciplinary action under A.R.S. Title 32, Chapter 11 or the rules in this Chapter.
- 28. "Lay person" means a person who is not a dentist, dental hygienist, dental assistant, denturist, or dental technician.
- 29. "Licensee" means a dentist, dental hygienist, or person who holds a restricted permit pursuant to A.R.S. § 32-1237.
- 30. "Local anesthesia" means is the elimination of sensations, such as pain, in one part of the body by the injection of an anesthetic drug.
- 31. "Nitrous oxide analgesia" means the use of nitrous oxide N2O/O2 (N2O/O2) used as an inhalation analgesic.
- 32. "Nonsurgical periodontal treatment" means plaque removal, plaque control, supragingival and subgingival scaling, root planing, and the adjunctive use of chemical agents.
- 33. "Nurse anesthetist" means a licensed nurse with special training in all phases of anesthesia.
  - "Outpatient" means an individual who receives treatment in a dental office or clinic.
- 34. "Oral or rectal conscious sedation" means the oral or rectal use of any is conscious sedation induced by an enterally or combination inhalation and enterally administered drug, element, or material to produce conscious sedation non-drug substance on an outpatient basis.
- 35. "Periodontal examination and assessment" means to collect and correlate clinical signs and patient symptoms that point to either the presence of or the potential for periodontal disease.
- 36. "Periodontal pocket" means a pathologic fissure bordered on one side by the tooth and on the opposite side by crevicular epithelium and limited in its depth by the epithelial attachment.
- 37. "Permanently disabled" means a dentist, dental hygienist, or denturist has totally withdrawn from the active practice of dentistry, dental hygiene, or denturism due to a physician's order because of a medical reason.
- 38. "Plaque" means a film-like sticky substance composed of mucoidal secretions containing bacteria and toxic products, dead tissue cells, and debris.

- 39. "Prescription-only device" means:
  - a. Any device that is limited restricted by the federal act, as defined in A.R.S. § 32-1901(31), restricted to use only under the supervision of a medical practitioner; or
  - b. Any device required by the federal act, as defined in A.R.S. § 32-1901(31), to bear on its label the legend, "Caution: federal law prohibits dispensing without prescription". "Rx Only."
- 40. "Prescription-only drug" means:
  - a. A drug which that, because of its toxicity or other potential for harmful effect, the method of its use, or the collateral measures necessary to its use, is not generally recognized among by experts, who are qualified by scientific training and experience to evaluate its the drug's safety and efficacy, as safe for use, except by or under the supervision of a medical practitioner;
  - b. Any  $\underline{A}$  drug that is limited by an approved new drug application under the federal act or A.R.S. § 32-1962 to use under the supervision of a medical practitioner;
  - e. Every A potentially harmful drug, the labeling of which does not bear or contain full and adequate directions for use by the consumer; or
  - d. Any A drug, other than a controlled substance, required by the federal act to bear contain on its label the legend "Caution: federal law prohibits dispensing without prescription." "Rx Only."
- 41. "President's designee" means the Board's executive director, an investigator, or another a Board member.
- 42. "Preventative and therapeutic agents" means substances used in relation to dental hygiene procedures that affect the hard or soft oral tissues to aid in preventing or treating oral disease.
- 43. "Prophylaxis" means a scaling and polishing procedure performed on patients with healthy tissues to remove coronal plaque, calculus, and stains.
- 44. "Recognized continuing dental education" means a program whose content directly relates to the art and science of oral health and treatment, provided by a recognized dental school as defined in A.R.S. § 32-1201(15), recognized dental hygiene school as defined in A.R.S. § 32-1201(14), or recognized school of denture technology as defined in A.R.S. § 32-1201(16), or sponsored by a national or state dental, dental hygiene, or denturist association, dental, dental hygiene, or denturist study club, governmental agency, or commercial dental supplier.
- 45. "Representative" means, for purposes of Article 15 only, a person recognized by the Board as authorized to act on behalf of a complainant or a party in proceedings governed by this Chapter.
- 46. "Restricted permit holder" means a dentist who meets the requirements of A.R.S. § 32-1237 and is issued a restricted permit by the Board.
- 47. "Root planing" means a definitive treatment procedure designed to remove cementum or surface dentin that is rough, impregnated with calculus, or contaminated with toxins or microorganisms.
- 48. "Scaling" means use of instruments on the crown and root surfaces of the teeth to remove plaque, calculus, and stains from these surfaces.
- 49. "Section 1301 permit" means a permit to administer general anesthesia and semi-conscious sedation, pursuant to under Article 13.
- 50. "Section 1302 permit" means a permit to administer conscious sedation, pursuant to <u>under</u> Article 13. "Section 1303 permit" means a permit to administer oral conscious sedation under Article 13.
- 51. "Semi-conscious sedation" means use of pharmacologic or non-pharmacologic methods, or a combination of the two methods, to induce a state of depressed consciousness accompanied by partial loss of protective reflexes, and the inability to continually maintain an airway independently or respond appropriately to physical stimulation or verbal command.
- 52. "Specialist" means, for purposes of Article 15 only, a licensee whose practice is limited to one of the following eight specialty categories recognized by the American Dental Association: endodontics, oral and maxillofacial surgery, orthodontics and dentofacial orthopedics, pediatric dentistry, periodontics, prosthodontics, oral pathology, or dental public health.
- 53. "Study Club" means a group of at least five Arizona licensed dentists, dental hygienists, or denturists who provide written course materials or a written outline for a continuing education presentation that meets the requirements of Article 12.
- 54. "Treatment records" means all documentation related directly or indirectly to the dental treatment of a patient.

### ARTICLE 13. GENERAL ANESTHESIA AND SEDATION

### **R4-11-1301.** General Anesthesia and Semi-conscious Sedation

**A.** To administer Before inducing general anesthesia by any means, or semi-conscious sedation by intravenous or intramuscular means, on an outpatient basis, a dentist shall possess a permit to administer general anesthesia and semi-conscious sedation ("Section 1301 permit") Section 1301 permit issued by the Board. A dentist shall renew a Section 1301 permit shall be renewed every three years by complying with R4-11-1305 R4-11-1306.

- **B.** To obtain or renew a Section 1301 permit, a dentist shall:
  - 1. Apply to the Board on the prescribed Submit a completed application on a form available from supplied by the Board office. The application form shall require information about each requirement to issue and renew a Section 1301 permit, as specified in that, in addition to the requirements of subsections (B)(2) and (B)(3), and R4-11-1305. R4-11-1306, includes:
    - a. The application form shall require general General information about the applicant such as:
      - i. name Name;
      - ii. home Home and office addresses and telephone numbers;
      - iii. limitations Limitations of practice;
      - iv. hospital Hospital affiliations;
      - v. denial Denial, curtailment, revocation, or suspension of hospital privileges; and
      - <u>vi.</u> <u>denial Denial</u> of membership in, <del>or</del> <u>denial of</u> renewal of membership in, or disciplinary action by <u>any dental</u> <u>regulatory body or a dental organization-; and</u>
      - vii. Denial of licensure by, denial of renewal of licensure by, or disciplinary action by a dental regulatory body;
        and
    - b. The application form shall require the dentist to sign an dentist's dated and signed affidavit stating that the information provided is true, and that the dentist has read and complied with the Board's statutes and rules. The dentist shall return the completed form to the Board office;
  - 2. Produce evidence that the dentist On forms provided by the Board, provide a dated and signed affidavit, that a facility where the dentist will administer general anesthesia or semi-conscious sedation:
    - a. Will administer general anesthesia and semi-conscious sedation in a facility containing Contains the following properly operating equipment and supplies:
      - i. anesthesia Anesthesia or analgesia machine;
      - ii. emergency Emergency drugs;
      - iii. electrocardiograph Electrocardiograph monitor;
      - iv. pulse Pulse oximeter;
      - v. cardiac Cardiac defibrillator;
      - vi. positive Positive pressure oxygen;
      - vii. suction; Suction equipment,
      - viii. laryngoscope Laryngoscope and blades;,
      - ix. endotracheal Endotracheal tubes;
      - x. Magill forceps;
      - xi. oral Oral airways;,
      - xii. stethoscope; Stethoscope, and
      - xiii. blood Blood pressure monitoring device; and
    - b. Has a supervised team of auxiliary Maintains a staff of supervised personnel for each facility in which the dentist will administer general anesthesia and semi-conscious sedation. A team shall be capable of handling procedures, problems complications, and emergency incidents. All team members personnel involved in administering and monitoring general anesthesia or semi-conscious sedation shall hold a current certification certificate in basic cardiopulmonary resuscitation (CPR) annually;
  - e.3. Holds Hold a valid license to practice dentistry in Arizona this state;
  - d.4. Maintains Maintain a current permit to prescribe and administer controlled substances in Arizona this state issued by the United States Drug Enforcement Administration; and
  - e.<u>5.</u> Has passed a course approved by <u>Hold a current certificate from</u> the American Heart Association or the American Red Cross on <u>in</u> advanced cardiac life support (ACLS) within the two years before submitting the permit application; and
  - 3.6. Meets Meet one or more of the following conditions:
    - a. Has completed Complete a full credit load, as defined by the training program, during one calendar year of training, in anesthesiology or related academic subjects, beyond the undergraduate dental school level in a training program described in R4-11-1304(A) R4-11-1305(A), offered by a hospital accredited by the Joint Commission of Accreditation of Hospitals Organization, or sponsored by a university accredited by the American Dental Association Commission on Dental Accreditation;
    - b. Is Be a Diplomate of the American Board of Oral and Maxillofacial Surgeons, or is eligible for examination by the American Board of Oral and Maxillofacial surgeons, or is a Fellow of the American Association of Oral and Maxillofacial surgeons, or is a Fellow of the American Dental Society of Anesthesiology or is eligible for examination by the American Dental Society of Anesthesiology; or
    - c. Employs Employ or works work with a licensed medical allopathic or osteopathic physician who is a member of the anesthesiology staff of an accredited hospital in Arizona this state and ensure that the anesthesiologist

remains on the dental facility premises until any patient given general anesthetic or semi-conscious sedation regains consciousness and is discharged.

- **C.** After submitting the application and written evidence of compliance with requirements outlined in subsection (B) to the Board, the dentist shall schedule an onsite evaluation by the Board in during which the dentist shall administer general anesthesia and semi-conscious sedation. After a dentist completes the application requirements and successfully completes the onsite evaluation, the Board shall issue the dentist a <u>Section</u> 1301 permit.
  - 1. The onsite evaluation team shall be <u>consist of</u> two dentists who are Board members, or Board designees. The onsite evaluation team shall look for the following:
    - a. The availability of equipment and personnel, pursuant to as specified in subsection (B)(2);
    - b. Proper administration of general anesthesia or parenteral semi-conscious sedation to a patient by the dentist before in the presence of the evaluation team; and
    - c. Successful responses by the dentist to oral examination questions from the evaluation team, about patient management, medical emergencies, and emergency medications;
    - d. Proper documentation of controlled substances, that includes a perpetual inventory log showing the receiving, administering, dispensing, and destroying of controlled substances; and
    - e. Proper recordkeeping as specified in subsection (D) by reviewing the records generated for the patient specified in subsection (C)(1)(b).
  - 2. The onsite evaluation of a subsequent facility in which general anesthesia or semi-conscious sedation is administered by a dentist who possesses a Section 1301 permit shall consist of the elements described in subsection (C)(1)(a) only as verified by may be waived by the Board staff upon receipt in the Board office of an affidavit verifying compliance with subsection (C)(1)(a).
- **D.** A dentist shall keep an anesthesia record for each general anesthesia and semi-conscious sedation administered. that:
  - 1. The record shall Shall include the following entries:
    - <u>a.</u> <u>pre-and Pre-operative and post-operative electrocardiograph reports;</u>
    - b. pre, post-, Pre-operative, post-operative, and intra-operative pulse oximeter readings;
    - c. blood Pre-operative and post-operative blood pressure and vital signs;
    - d. intra-operative Intra-operative blood pressures; and
    - e. a A list of all medications given, with dosage and time intervals; and
  - 2. The record may May include the following entries:
    - a. route Route and site of administration;
    - <u>b.</u> <u>type</u> <u>Type</u> of catheter or portal with gauge;
    - c. <u>Indicate</u> nothing by mouth or <u>time of last intake</u> noted of food or water;
    - d. consent Consent form; and
    - e. time Time of discharge and status, including name of escort.
- **E.** A dentist, who has obtained obtains a Section 1301 permit to administer general anesthesia and semi-conscious sedation, may employ a nurse anesthetist to administer general anesthesia and or semi-conscious sedation under the dentist's direct supervision.
- **F.** A dentist who has obtained obtains a Section 1301 permit is also authorized to administer may also induce conscious sedation without obtaining a Section 1302 permit.

### **R4-11-1302.** Conscious Sedation

- A. A dentist who possesses a Section 1301 permit is also authorized to administer may also induce conscious sedation. To administer Before inducing conscious sedation by intravenous or intramuscular means on an outpatient basis, a dentist who does not possess a Section 1301 permit shall possess a permit to administer conscious sedation ("Section 1302 permit") Section 1302 permit issued by the Board. The A dentist shall renew a Section 1302 permit shall be renewed every three years by complying with R4-11-1305 R4-11-1306.
- **B.** To obtain or renew a Section 1302 permit, the dentist shall:
  - 1. Apply to the Board on the prescribed Submit a completed application on a form available from supplied by the Board office. The application form shall require information regarding that, in addition to the requirements to obtain and renew a Section 1302 permit, as specified in of subsections (B)(2) and (B)(3) and R4-11-1305. R4-11-1306, includes:
    - a. The application form shall require general General information about the applicant such as:
      - i. name Name;
      - ii. home Home and office addresses and telephone numbers;
      - iii. limitations Limitations of practice;
      - iv. hospital Hospital affiliations;
      - v. denial Denial, curtailment, revocation, or suspension of hospital privileges; and
      - <u>vi.</u> <u>denial Denial</u> of membership in, <u>or denial of</u> renewal of membership in, or disciplinary action by <u>any dental</u> regulatory body or <u>a</u> dental organization.; <u>and</u>

- vii. Denial of licensure by, denial of renewal of licensure by, or disciplinary action by a dental regulatory body; and
- b. The application form shall require the dentist to sign an dentist's dated and signed affidavit stating that the information provided is true, and that the dentist has read and complied with the Board's statutes and rules. The dentist shall return the completed form to the Board office; and
- 2. Produce evidence that the dentist On forms provided by the Board, provide a dated and signed affidavit, that a facility where the dentist will administer conscious sedation by intravenous or intramuscular route:
  - a. Will administer conscious sedation intravenously or intramuscularly in a facility containing Contains the following properly operating equipment and supplies:
    - i. emergency Emergency drugs;
    - ii. positive Positive pressure oxygen;
    - iii. stethoscope; Stethoscope,
    - iv. suction; Suction equipment,
    - v. nasopharyngeal Masopharyngeal tubes;
    - vi. pulse Pulse oximeter;
    - vii. oropharyngeal Oropharyngeal tubes;, and
    - viii. blood Blood pressure monitoring device; and
  - b. Maintains a staff of supervised personnel capable of handling procedures, complications, and emergency incidents, for each facility in which the dentist will administer conscious sedation. At including at least one staff member, who:
    - i. Holds a current certificate in basic cardiopulmonary resuscitation (CPR);
    - <u>ii.</u> <u>Is</u> present during the <u>conscious sedation</u> procedure<del>, shall be certified in basic cardiac life support (CPR) annually;</del> <u>and</u>
    - iii. After the procedure, monitors the patient until discharge;
- e.3. Holds Hold a valid license to practice dentistry in Arizona this state;
- d.4. Maintains Maintain a current permit to prescribe and administer controlled substances in Arizona this state issued by the United States Drug Enforcement Administration;
- e.<u>5.</u> Has passed a course approved by <u>Hold a current certificate from</u> the American Heart Association or the American Red Cross on <u>in</u> advanced cardiac life support (ACLS) within the two years before submitting the permit application; and
- <u>f.6.</u> <u>Has participated Participate</u> in 60 clock hours of Board\_approved undergraduate, graduate, or postgraduate education within the three years before submitting the permit application, <u>which includes that covers</u> training in basic conscious sedation, including:
  - a. administration Administration of parenteral sedative medications to at least ten patients;
  - b. physical Physical evaluation;
  - c. management Management of medical emergencies;
  - d. The importance of and techniques for maintaining proper documentation; and
  - e. monitoring, Monitoring and the use of monitoring equipment.
- **C.** After submitting the application and written evidence of compliance with requirements outlined in subsection (B) to the Board, the dentist shall schedule an onsite evaluation by the Board in during which the dentist shall administer conscious sedation. After a dentist completes the application requirements and successfully completes the onsite evaluation, the Board shall issue the dentist a <u>Section</u> 1302 permit.
  - 1. The onsite evaluation team shall be <u>consist of</u> two dentists who are Board members, or Board designees. The onsite evaluation team shall look for the following:
    - a. The availability of equipment and personnel pursuant to as specified in subsection (B)(2);
    - b. Proper administration of conscious sedation to a patient by the dentist before in the presence of the evaluation team; and
    - c. Successful responses by the dentist to oral examination questions from the evaluation team, about patient management, medical emergencies, and emergency medications; and
    - d. Proper documentation of controlled substances, that includes a perpetual inventory log showing the receiving, administering, dispensing, and destroying of controlled substances; and
    - e. Proper recordkeeping as specified in subsection (D) by reviewing the records generated for the patient specified in subsection (C)(1)(b).
  - 2. The onsite evaluation of a subsequent facility in which conscious sedation is administered by a dentist who possesses a Section 1302 permit shall consist of the elements described in subsection (C)(1)(a) only, as verified by may be waived by the Board staff upon receipt in the Board office of an affidavit verifying compliance with subsection (C)(1)(a).

- **D.** A dentist shall keep an anesthesia record for each conscious sedation administered. that:
  - 1. The record shall include the following entries:
    - <u>a.</u> <u>pre, post-, Pre-operative, post-operative,</u> and intra-operative pulse oximeter readings;
    - <u>b.</u> <u>pre-and postoperative</u> <u>Pre-operative</u> and <u>post-operative</u> blood pressure and vital signs;
    - c. intra operative Intra-operative blood pressures; and
    - d. a A list of all medications given, with dosage and time intervals: and
  - 2. The record may May include the following entries:
    - a. pre-Pre-operative and post-operative electrocardiograph report;
    - b. route Route and site of administration;
    - c. type Type of catheter or portal with gauge;
    - <u>d.</u> <u>Indicate</u> nothing by mouth or <u>time of</u> last intake <del>noted</del> <u>of food or water</u>;
    - e. consent Consent form; and
    - <u>f.</u> <u>time</u> Time of discharge and status, including name of escort.
- **E.** A dentist who has obtained obtains a Section 1302 permit to administer conscious sedation, may employ a nurse anesthetist to administer conscious sedation under the dentist's direct supervision.

### R-4-11-1303. Oral Conscious Sedation

- A. Before inducing oral conscious sedation on an outpatient basis, a dentist shall possess a Section 1303 permit issued by the Board, unless the dentist qualifies for a permit under subsection (C). A dentist shall renew a Section 1303 permit every three years by complying with R4-11-1306.
  - 1. A dentist who possesses a Section 1301 or Section 1302 permit may also induce oral conscious sedation without obtaining a Section 1303 permit.
  - 2. The administration of an anti-anxiety drug is not combination inhalation-enteral conscious sedation if:
    - a. Only one dose of one anti-anxiety drug is administered;
    - b. The intent of administering the anti-anxiety drug is anxiolysis only; and
    - c. The administered dose of anti-anxiety drug is within the current guidelines for anxiolysis dosage on the manufacturer's package insert or other recognized drug reference.
- **B.** To obtain or renew a Section 1303 permit, a dentist shall:
  - 1. Submit a completed application on a form supplied by the Board office that, in addition to the requirements of subsections (B)(2) and (B)(3) and R4-11-1306, includes:
    - <u>a.</u> General information about the applicant such as:
      - i. Name;
      - ii. Home and office addresses and telephone numbers;
      - iii. Limitations of practice;
      - iv. Hospital affiliations;
      - v. Denial, curtailment, revocation, or suspension of hospital privileges;
      - <u>vi.</u> Denial of membership in, denial of renewal of membership in, or disciplinary action by a dental organization; and
      - <u>vii.</u> Denial of licensure by, denial of renewal of licensure by, or disciplinary action by a dental regulatory body; and
    - b. The dentist's dated and signed affidavit stating that the information provided is true, and that the dentist has read and complied with the Board's statutes and rules;
  - 2. On forms provided by the Board, provide a dated and signed affidavit, that a facility where the dentist will administer oral conscious sedation:
    - a. Contains the following properly operating equipment and supplies:
      - i. Emergency drugs,
      - ii. Positive pressure oxygen,
      - iii. Precordial stethoscope,
      - iv. Suction equipment,
      - v. Pulse oximeter,
      - vi. Blood pressure monitoring device, and
      - vii. Auxiliary lighting; and
    - <u>b.</u> <u>Maintains a staff of supervised personnel capable of handling procedures, complications, and emergency incidents, including at least one staff member who:</u>
      - i. Holds a current certificate in basic cardiopulmonary resuscitation (CPR);
      - ii. Is present during the oral conscious sedation procedure; and
      - iii. After the procedure, monitors the patient until discharge;
  - 3. Hold a valid license to practice dentistry in this state;

- 4. Maintain a current permit to prescribe and administer controlled substances in this state issued by the United States Drug Enforcement Administration;
- 5. Hold a current certificate in basic cardiopulmonary resuscitation (CPR); and
- <u>6. Meet one or both of the following:</u>
  - a. Complete a Board-approved post-doctoral residency program that includes documented training in oral conscious sedation; or
  - b. Participate in 30 clock hours of Board-approved undergraduate, graduate, or post-graduate education in oral conscious sedation within the five years before submitting the permit application, that include:
    - i. Training in basic oral conscious sedation,
    - ii. Administration or observation of the oral conscious sedation of at least five patients,
    - iii. Pharmacology,
    - iv. Physical evaluation,
    - v. Management of medical emergencies,
    - vi. The importance and techniques for maintaining proper documentation, and
    - vii. Monitoring and the use of monitoring equipment.
- C. After submitting the application and written evidence of compliance with requirements in subsection (B) to the Board, the dentist shall schedule an onsite evaluation by the Board. After a dentist completes the application requirements and successfully completes the onsite evaluation, the Board shall issue the dentist a Section 1303 permit.
  - 1. The onsite evaluation team shall consist of two dentists who are Board members, or Board designees. The onsite evaluation team shall look for the following:
    - a. The availability of equipment and personnel as specified in subsection (B)(2);
    - <u>proper documentation of controlled substances, that includes a perpetual inventory log showing the receiving, administering, dispensing, and destroying of controlled substances; and</u>
    - c. Proper recordkeeping as specified in subsection (D) by reviewing the forms that document the anesthesia record.
  - 2. The evaluation of a subsequent facility in which oral conscious sedation is administered by a dentist who possesses a Section 1303 permit may be waived by the Board staff upon receipt in the Board office of an affidavit verifying compliance with subsection (C)(1)(a).
- **D.** A dentist who induces oral conscious sedation shall keep an anesthesia record for each oral conscious sedation procedure that:
  - 1. Includes the following entries:
    - <u>a.</u> <u>Pre-operative, post-operative, and intra-operative pulse oximeter oxygen saturation and pulse rate readings;</u>
    - b. Pre-operative and post-respiratory rate;
    - c. Pre-operative and post-operative blood pressure;
    - d. <u>Documented reasons for not taking vital signs if a patient's behavior or emotional state prevents monitoring personnel from taking vital signs;</u>
    - e. List of all medications given, including dosage and time intervals;
    - f. Patient's weight;
    - g. Consent form;
    - h. Special notes, such as, nothing by mouth or last intake of food or water; and
    - i. Time of discharge and status, including name of escort; and
  - 2. May include the following entries:
    - a. Pre-operative and post-operative electrocardiograph report; and
    - b. <u>Intra-operative blood pressures.</u>
- E. To continue inducing oral conscious sedation after May 1, 2004, a dentist licensed in this state who has been inducing oral conscious sedation for at least three years before May 1, 2003 may qualify and obtain a Section 1303 permit without meeting the educational requirements of subsection (B)(6) by complying with the following:
  - 1. Apply for a Section 1303 permit on or before May 1, 2004;
  - 2. Comply with subsections (B(1) through (B)(5); and
  - 3. Provide the Board with the following:
    - a. Twelve oral conscious sedation cases per year for the previous three years;
    - b. Documentation of twelve continuing education hours in oral conscious sedation in the previous three years; and
    - c. Records from the last ten consecutive oral conscious sedation cases with an affidavit attesting that the records are the licensee's last ten consecutive cases.

# R4-23-1303. R4-11-1304. Reports of Adverse Occurrences

If a death, or incident causing a patient temporary or permanent physical or mental injury or requiring medical intervention, occurs in an outpatient facility as a direct result of the administration of general anesthesia, semi-conscious sedation, or oral conscious sedation, the permit holder and the treating dentist involved shall submit a complete report of the incident to the Board within ten days after its the occurrence.

### R4-11-1304. R4-11-1305. Education

- **A.** To obtain a Section 1301 permit by satisfying the education requirement of R4-11-1301(B)(6), a dentist shall successfully complete an advanced graduate or post-graduate education program (postgraduate or graduate) in pain control.
  - 1. The program shall include instruction in the following subject areas:
    - a. Anatomy and physiology of the human body and its response to the various pharmacologic agents used in pain control;
    - b. Physiological and psychological risks for the use of various modalities of pain control;
    - c. Psychological and physiological need for various forms of pain control and the potential response to pain control procedures;
    - d. Techniques of local anesthesia, sedation, and general anesthesia, and psychological management and behavior modification, as they relate to pain control in dentistry; and
    - e. Handling emergencies and complications related to pain control procedures, including the maintenance of respiration and circulation, immediate establishment of an airway, and cardiopulmonary resuscitation.
  - 2. The program shall consist of didactic and clinical training. The didactic component of the program shall:
    - a. be Be the same for all dentists, whether general practitioners, or specialists: and
    - b. The didactic component shall include Include each subject area listed in subsection (A)(1).
  - 3. The dentist program shall complete provide at least one calendar year of training as prescribed in R4-11-1301(B)(3)(a) (B)(6)(a).
- **B.** To maintain a Section 1301 or 1302 permit pursuant under to R4-11-1301 or R4-11-1302, a dentist shall:
  - <u>1.</u> participate Participate in 12 clock hours of continuing education every three years. The education shall be in one or more of the following areas:
    - a. general General anesthesia;
    - b. conscious Conscious sedation;
    - c. physical Physical evaluation;
    - d. medical Medical emergencies;
    - e. monitoring Monitoring and use of monitoring equipment; or
    - <u>f.</u> pharmacology Pharmacology of utilized drugs and agents. non-drug substances used in general anesthesia or conscious sedation; and
  - 2. In addition to these 12 hours, the dentist shall pass a course approved by Hold a current certificate from the American Heart Association or American Red Cross on in advanced cardiac life support (ACLS), at intervals described in R4-11-1301(B)(2)(e) and R4-11-1302(B)(2)(e).
- C. To maintain a Section 1303 permit issued under R4-11-1303, a dentist shall:
  - 1. Participate in six clock hours of continuing education every three years in one or more of the following areas:
    - a. Oral conscious sedation,
    - b. Physical evaluation,
    - c. Medical emergencies,
    - d. Monitoring and use of monitoring equipment, or
    - e. Pharmacology of oral conscious sedation drugs and non-drug substances, and
  - 2. Hold a current certificate in basic cardiopulmonary resuscitation (CPR).

# R4-11-1305. R4-11-1306. Renewal of Permit

- A. To renew a Section 1301, or 1302, or 1303 permit before December 31 of every third year, a dentist shall;
  - 1. provide Provide written documentation of compliance with the applicable continuing education requirements, as prescribed in R4-11-1304 R4-11-1305;
  - 2. by submitting the Before December 31 of the year the permit expires, submit a completed application form to on a form supplied by the Board office as described in Article 13. R4-11-1301, R4-11-1302, or R4-11-1303; and
  - 3. Not less than 90 days before the expiration of a dentist's current permit, the dentist shall arrange for a new onsite evaluation as described in Article 13 R4-11-1301, R4-11-1302, or R4-11-1303.
- **B.** After a dentist has successfully completed completes the evaluation and submitted submits the required affidavits, the Board shall issue a renewal Section 1301, or 1302, or 1303 permit.
- **B-**C. The Board may stagger due dates for renewal applications.